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EXAMINER				
UNDERDAHL, THANE E				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/570,835

Applicant(s)

ARZT ET AL.

Examiner

THANE UNDERDAHL

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date 12/20/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/20/07 has been entered.

This Office Action is in response to the Applicant's request for continued examination. Claims 5-11 are pending. No claims are withdrawn. No Claims are cancelled. Claim 5 has been amended. No claims are new.

Claim Rejections - 35 USC § 112

In the response submitted by the Applicant the 35 U.S.C § 112 rejection of claim 5-10 is withdrawn in light of the Applicant's amendment to the specification and figures also the submission of the translation Excerpts of the dissertation of Micheal R. Schoen received 12/20/07 .

New 35 USC § 112 Rejections Necessitated by Amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. In claim 5 the limitation "wherein said organ is

Art Unit: 1651

maintained by the storage fluid in a floating state inside said protective cover” is critical or essential to the practice of the invention, is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The diagram on Figure 1 the organ while enclosed in the protective cover appears firmly supported on the wall that has the perfusion and inlet and outlet ports. Furthermore, for an object to float it would need to have a density lower than the media in which it is suspended. There is no mention of the density of the liquid in which the organ is suspended. Clarification is required.

Because claims 6-11 are depend from indefinite claim 5 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, first paragraph.

Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 5 includes limitations that impart that the VSP-circuit clearly has two subcircuits that were listed above and that these subcircuits have a specific relationship to each other including how DSC is linked to the PCS and that the DCS dialyzes the perfusate for the PCS. However the specification, including Figure 1, does not teach or diagram how the subcircuits are connected to accomplish this task. While the Applicant has submitted prior art from the dissertation of Dr. Schoen showing a probable method to connect these circuits, these were not

incorporated by reference into the specification. As written one of ordinary skill in the art would not have adequate guidance to make and use the storage system presented in this application.

Because claims 6-11 are depend from indefinite claim 5 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As claim 5 is currently written the extracorporeal storage system includes a vitality-preserving fluid circuit (**VPF-Circuit**). This VPF-Circuit includes two sub-circuits:

- o Dialysate circulation system (**DCS**) "that circulates a dialysate for dialyzing said perfusate"
- o Perfusate circulation system (**PCS**) "that circulates a perfusate for perfusion of said extracorporeal organ"

It is unclear to the Examiner how the Dialysate and the Perfusate are different solutions. On the one hand the claim states that the "dialysate" is for "dialyzing said perfusate". However, this is confusing when taken into context the broad use term for dialysis, which requires a diffusion of a substance between a semipermeable membrane. If the

Art Unit: 1651

dialysate is a liquid it is unclear how this liquid is dialyzing the perfusate since it is not apparent to the Examiner how the dialysate incorporates the semipermeable membrane. Clarification is required. Furthermore looking at the Figures 1 and 10 in the dissertation of Dr. Schoen et al. it appears that the spent perfusate exiting the organ is split into two streams. One is sent to a dialyzer via pump 3B (see Figure 10) the stream is remixed with the dialysate via pump 2A (see Figure 10). So even with the additional evidence presented of what one of ordinary skill in the art would be understand, claim 5 remains indefinite since there remains some ambiguity concerning the link between the relationship of the perfusate and dialysate or the circuits for these fluids.

Because claims 6-11 are depend from indefinite claim 5 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

In the interest of compact prosecution considering the above rejections, claim 5 will read as follows:

"A storage system for extracorporeal storage of an organ comprising:
an organ perfusion chamber for storing an extracorporeal organ;
a vitality-preserving fluid circuit for circulating a vitality-preserving fluid (VSP) into said extracorporeal organ stored in said organ perfusion chamber, said vitality preserving fluid circuit comprises a dialysate circulation system (DSC) and a perfusate circulation system (PCS) that administers and recycles the vitality preserving liquid as it flows through the organ;

a storage fluid inside the organ perfusion chamber that serves as a reservoir for the vitality-preserving fluid that flows through the organ;

a protective cover that receives the extracorporeal organ and provides a complete barrier to the storage fluid;

wherein the protective cover that holds the extracorporeal organ is floating on the storage fluid in the organ perfusion chamber.”

Response to Applicant's Arguments-Double Patenting

The Applicant has requested that the provisional double-patenting rejections made in the previous Office Action be held in abeyance. While this is within the purview of the Applicant the rejection will stand until that time or until further arguments are presented.

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the Applicant, the 35 U.S.C § 102 (b) rejection of claims 5 and 6 over Brasile were considered but not found persuasive.

The Applicant argues that the “organ is not maintained in a floating state. Rather, liquid is drained from the organ and drips down into a reservoir (38) beneath an organ support”. However Brasile expressly teaches that “Organ support member 36 is adapted to inhibit movement of the organ within the container. Organ support member may be made of a...mesh like fabric which suspends the organ in a sling-like fashion”. Looking at Figure 1 of Brasile shows that 36, does indeed create a barrier between the

Art Unit: 1651

reservoir 38 and the organ 40. If 36 were a sling it would float or suspend the organ over the reservoir. Also while Figure 1 shows that the barrier 36 is porous (37), this is simply an illustrative example used by Brasile since she further teaches that her invention uses a tube and not a porous barrier (Brasile, paragraph 74) thus Brasile teaches a complete barrier with the reservoir. Therefore the rejection stands and is repeated below with modifications to address the amendments to the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 6 and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Brasile (U.S. Patent Application Publication # 2002/0012988).

These claims are drawn to a system for extracorporeal storage of organs. The system further comprises a temperature control device in the organ perfusion chamber to control the temperature of the storage fluid.

Brasile teach a system for the extracorporeal storage of organs that includes a perfusion chamber and a dialysis machine that circulates and purifies the vitality preserving storage liquid (Fig 1 and paragraph 23). The organ is held in a pouch or sack made of impermeable plastic such as silicon (paragraph 67) in a sling like fashion that encloses and floats the organ over the reservoir (paragraph 66 and 67). The chamber includes a reservoir that replenishes the fluid circuit as it flows over the organ and is

Art Unit: 1651

purified. The system includes a temperature control device to control the temperature of the vitality preserving storage fluid inside the perfusion chamber (page 2 paragraph 12).

Therefore the reference anticipates claims 5, 6 and 11.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 5-9 and 11 over Brasile and claims 5-11 over Brasile in view of Bacchi et al. were considered but not found persuasive.

Applicants rely on the arguments used in traversing the above rejection to also traverse this rejection without additional arguments. However, as explained above, the previous rejection stands. Therefore, the response set forth above to arguments also applies to this rejection.

Therefore the rejections stand and are repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9 and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brasile as applied to claims 5 and 6 in the above rejection.

The description and rejection of claims 5, 6 and 11 are listed in the 35 U.S.C § 102(b) rejection above.

Claim 8 limits the temperature control device is integrated into the wall of the organ perfusion chamber. Claim 9 limits that the temperature control device comprises temperature control loops embedded in the organ perfusion chamber.

Brasile teach an organ perfusion chamber with a heat exchanger and a temperature sensor situated within the organ perfusion chamber (page 7, paragraph 60). However Brasile does not specifically teach a temperature control device integrated into the wall of the organ perfusion chamber. However based on the disclosure by Brasile it would be prima facie obvious at the time of filing to modify the invention to integrate the temperature control device into the wall, since Brasile already places the temperature control sensors of the device in the perfusion chamber. Furthermore M.P.E.P. § 2144.04 B state that making a device integral "would be merely a matter of obvious engineering choice" and as such is prima facie obvious to make the temperature control device integral with the perfusion chamber.

Also since Brasile teach that the temperature controller maintains the temperature between 25-37 °C based on the input it receives from the sensor (page 7, paragraph 60) it is obvious that one of ordinary skill in the art would recognize that the system contains temperature control feedback loops.

Claim 7 limits the temperature control device to a heating mat.

Brasile teach an organ perfusion chamber with a heat exchanger and a temperature sensor situated within the organ perfusion chamber (page 7, paragraph 60). Brasile does not teach that the heat exchanger is a heating mat. However it would have been obvious to someone skilled in the art at the time the invention was made that

multiple methods can be used to heat the storage solution included a water heater to circulate warmed water around the reservoir (page 7, paragraph 60). One of ordinary skill in the art would recognize that a heat exchanger can include heating elements as well as a heating mat since both are known in the art to heat liquid as taught by Cooksley et al. (col 2, lines 65-70). Therefore it would be *prima facie* obvious to use a heating mat as a heat exchanger for the perfusion chamber. The reference above render obvious claims 5-9 and 11.

Claims 5-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brasile as applied to claims 5-9, and 11 above, and further in view of Bacchi et al. (U. S. Patent # 5,285,657, 1994).

The description and rejection of claims 5-9 and 11 are listed in the 35 U.S.C § 103(a) rejection above by Brasile et al. Claim 10 further limits that the organ perfusion chamber is hermetically sealed against fluid and pressure.

While Brasile does teach an organ perfusion chamber in combination with a temperature control device and dialysis system he does not specifically teach that the organ perfusion chamber is hermetically sealed against fluid and pressure. He does teach that it is important to minimize perfusion contamination due to contact with air (Brasile, page 9 paragraph 78) which provides motivation to hermetically (airtight) seal the chamber. However it would have been obvious to someone skilled in the art at the time the invention was made to make the organ perfusion chamber hermitically sealed in view of Bacchi et al. who teach an insulated organ perfusion chamber (Bacchi, col 1,

lines 45-50) for extracorporeal organ transport (Bacchi, see abstract). Bacchi et al. teach that the lid of this chamber is hermetically sealed (col 7, line 45-50).

It would have been obvious to someone skilled in the art to modify the invention of Brasile with the hermetically sealed lid taught by Bacchi et al. The motivation is provided by Brasile who desires minimal contact with air and the organ. Bacchi et al. provides the reasonable expectation of success by making an organ perfusion chamber that is hermetically sealed.

Furthermore, M.P.E.P. § 2144.06 holds that it is obvious that since both devices are known for the same purpose (extracorporeal organ storage) it would be obvious to combine the elements of both devices to form a third device used for the same purpose.

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 5-11 are not allowable.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Art Unit: 1651

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

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